

FEB - 3 2005

510(k) SUMMARY

A. Submitter Information:

Submitter: MEDCOMP®
1499 Delp Drive
Harleysville, PA 19438
(215) 256-4201 Telephone
(215) 256-9191 Fax
Contact: Jean Callow
Date Prepared: February 2, 2004

B. Trade Name: Medcomp Split-Cath® II
Common Name: Hemodialysis Catheter, Implanted
Classification: MSD
C.F.R. Section: 876.5540

C. Predicate Device: K020465 Medcomp Ash Split-Cath II, K971925 Medcomp Bio-Flex CS Cath with Adjustable Cuff and K022678 Medcomp Split-Stream SC4

D. Device Description:

The Medcomp Split-Cath II is a polycarbonate/polyurethane, double lumen catheter used to remove and return blood through two-segregated lumen passages. Both lumens are "D" shaped, tapered at the distal tip, with eight side holes. The distal venous lumen extends beyond the arterial lumen to reduce recirculation. The fixed polyester cuff allows for tissue ingrowth for long term placement.

The arterial and venous lumens are designed to be split, or peeled apart, prior to insertion to provide two free-floating lumens within the vessel. The side holes are orientated to allow 360-degree arterial uptake and venous return. The lumens are connected to the extensions via a soft pliable hub with suture wing. Red and blue luer connectors and clamps identify the arterial and venous extensions. Priming volume information is printed on an identification ring housed within the extension line clamp.

E. Intended Use:

The Medcomp Split-Cath II is indicated for use in attaining long-term vascular access for hemodialysis and apheresis. It may be inserted percutaneously and is primarily placed in the internal jugular vein. Alternate insertion site is the subclavian vein.

F. Comparison to Predicate Device:

The technological characteristics of the Split-Cath II are substantially equivalent to the predicate devices in terms of intended use, insertion method, anatomical location, design, performance, labeling, manufacturing process and method of sterilization.

The design specifications are identical to that of the Ash Split- Cath II predicate device. The difference between the proposed device and the predicate is the addition of a second vendor for the lumen material. The proposed device and predicate device lumens are manufactured from polyurethane, the material formulations are the same.

G. Performance Data:

In Vitro performance data for the Medcomp Split Cath II, including tensile strength, joint strength, leakage, recirculation, flow performance, flexural and lumen peel demonstrate that this device is substantially equivalent to the legally marketed Ash Split-Cath II catheter.

Biocompatibility testing on the Split-Cath II demonstrates the lumen materials meet the requirements of USP XXII for a permanent contact device.

Clinical data was not deemed necessary since substantial equivalence is addressed by way of comparison to a legally marketed device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FEB - 3 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Jean Callow
Regulatory Specialist
Medcomp®
1499 Delp Drive
HARLEYSVILLE PA 19438

Re: K040318
Trade/Device Name: Medcomp® Split Cath® II
Regulation Number: 21 CFR §876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: III
Product Code: 78 MSD
Dated: January 20, 2005
Received: January 25, 2005

Dear Jean Callow:


We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the tray have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. *Please note:* If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your tray. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration (21 CFR Part 807); listing (21 CFR Part 807), labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market. If you desire specific advice for your device on the labeling regulation, please contact the Office of Compliance at (240)276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



for Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number:

Device Name: Medcomp® Split Cath® II

Indications for use:

The Medcomp® Split-Cath® II is indicated for use in attaining chronic (long-term) vascular access for hemodialysis and apheresis. It may be inserted percutaneously and is ideally placed in the internal jugular vein of an adult patient. Alternate insertion site includes the subclavian vein as required.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter

David A. Eyrum
(Division Sign-Off)

Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number K040318

(Optional Format 1-2-96)